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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,316	03/29/2007	Alain Aaron	GER-0818	5091
23413 7590 03/23/2009 CANTOR COLBURN, LLP 20 Church Street 22nd Floor Hartford, CT 06103				
EXAMINER FISHER, ELANA BETH				
ART UNIT 3733		PAPER NUMBER		
NOTIFICATION DATE 03/23/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

Office Action Summary

Application No.

10/583,316

Applicant(s)

AARON, ALAIN

Examiner

ELANA B. FISHER

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of GROUP I, claims 1 and 3-13 in the reply filed on December 11, 2008 is acknowledged.
2. Claim 14 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 11, 2008.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

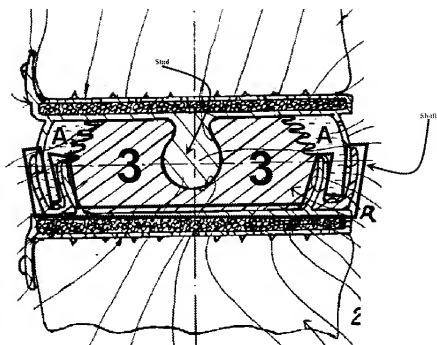
Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 8 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Huang (U.S. Publication 2004/0193273).

- a. Regarding claim 1, Huang discloses an intervertebral disc prosthesis (FIG 2) comprising two rigid half-shells in the form of cups or plates (1, 2) which are each intended to be fixed to one of two vertebrae adjacent to an intervertebral disc to be replaced. The two half-shells enclose a compression pad (3, A) made of at least two materials of different hardness (Paragraph [0034] – Paragraph [0038]), wherein one of the two half-shells (2) comprises, in its central zone, a shaft (24; see diagram provided) which is oriented toward the second half-shell (1), with the second half-shell comprising, in its central zone, a stud (14) whose cross section is smaller than that of the shaft and which is oriented toward the first half-shell and is engaged in the shaft of the latter, and additionally a sum of the lengths of the shaft and of the stud (14) is greater than the distance between the two half-shells (1, 2), with the compression pad (3, A) being disposed between the two half-shells, including a volume (3; see diagram provided) situated between the shaft and the stud, wherein volumes disposed outside (A) and inside (3) of the shaft, respectively, are filled with compressible materials of different hardness.
- b. Regarding claim 8, each half-shell (1, 2) comprises, on its outer face, points (121, 221) intended to promote its fixation to a vertebra (FIG 1).



6. Claims 3, 5-7 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273) as applied to claims 1 and 3 above.

- a. Regarding claim 3, the compressible material situated outside the shaft is harder than the material situated inside the shaft (Paragraph [0034] – Paragraph [0038]).
- b. Regarding claim 5, Huang discloses an intervertebral disc prosthesis according to claim 3 above, however fails to disclose the material of the compression pad that is situated outside the shaft (A; see diagram provided). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the compressible material situated outside the shaft be a synthetic material of the polycarbonate urethane type, since it has been held to be within the general skill of a

worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

c. Regarding claim 6, Huang discloses an intervertebral disc prosthesis according to claim 3 above, however fails to disclose the material of the compression pad that is situated inside in the shaft (3; see diagram provided). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the compressible material situated inside the shaft be a mixture of two-component silicone elastomer and of an encapsulating copolymer whose blowing agent is isobutane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

d. Regarding claim 7, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to distinctly state that the two half-shells (1, 2) are made of a titanium based alloy (Paragraph [0025]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the two half-shells be made of a titanium-based alloy, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

e. Regarding claim 11, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose that the stud (14) and shaft (24; see diagram provided) have a trapezoidal cross section. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the

stud and shaft with a cross-section having a trapezoidal shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

f. Regarding claim 12, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose that the stud and the shaft have a non-circular cross-section. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the stud and shaft with a cross-section having a non-circular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a forming edge in the heating portion or clamp. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Regarding the above claims, see the figures corresponding to claims 1 and 3 above.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273) as applied to claim 3 above, and further in view of Gauchet (U.S. Patent 6,582,468).

a. Regarding claim 4, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose the Shore-A hardness of the compressible material inside and outside of the shaft. Gauchet discloses an intervertebral disc implant with a compressible pad that has a Shore-A hardness of between 60 and 100 (Column 3, lines 7-8). It would have been obvious to one having ordinary skill in the art at the time

the invention was made to have the Shore-A hardness of the compressible material outside of the shaft to be between 60 and 100, and additionally the Shore-A hardness of the compressible material inside the shaft to be between 25 and 30, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273) as applied to claim 1 above, and further in view of Hedman et al. (U.S. Patent 4,759,769).

a. Regarding claim 9, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose that there are lugs on the face of each half-shelf (1, 2). Hedman et al. disclose an intervertebral disc prosthesis that comprises lugs (46) on the inner face of two half-shells (30, 50). It therefore would have been obvious to one skilled in the art to modify the intervertebral disc prosthesis taught by Huang with the addition of lugs to the inner face of the half-shells, as is taught by Hedman et al. because the lugs provide the advantage of aiding in securing the half-shells to the vertebrae, which in-turn aid in attachment and implantation of the compression pad to the intervertebral disc space.

Regarding the above claim, see the figures corresponding to claim 1 and figure 1 in Hedman et al.

9. Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (U.S. Publication 2004/0193273) as applied to claim 1 above, and further in view of Errico et al. (U.S. Publication 2003/0074067).

a. Regarding claim 10, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose the means by which the stud (14) is fixed to the half-shell (1). Errico et al. discloses an intervertebral disc prosthesis with a stud (28) that is fixed to a half-shell (10) by being screwed into a through-hole (26). It therefore would have been obvious to one skilled in the art to modify the prosthesis taught by Huang with the fixation means of screwing the stud into the top of the half-shell, as is taught by Errico et al. because screwing the stud into the half-shell is an alternative fixation means which accomplishes the goal of attachment of the stud, while keeping the intervertebral disc prosthesis functionally and mechanically analogous to another fixation means.

b. Regarding claim 13, Huang discloses an intervertebral disc prosthesis according to claim 1 above, however fails to disclose a coating on the outer surfaces of the half-shells. Errico et al. discloses an intervertebral disc prosthesis that comprises a coating on the outer surfaces of the half-shells (Paragraph [0110]) for ensuring primary osseous fixation. It therefore would have been obvious to one skilled in the art to modify the intervertebral disc prosthesis taught by Huang with the addition of a coating as is taught by Errico et al. because the coating provides the advantage of further aiding in bone fixation, while keeping the functional and structural features of the prosthesis analogous to that taught by Huang.

Regarding the above claims, see the figures corresponding to claim 1 and figure 1i in Errico et al.

Response to Arguments

10. Applicant's arguments with respect to claims 1, 3-13 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELANA B. FISHER whose telephone number is (571)270-3643. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elana B Fisher/
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733